



About This Policy

Effective Dates:

08-15-2016

Last Updated:

01-04-2017

Responsible University Administrator:

Vice President for Research

Policy Contact:

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Scope

This policy applies to all Indiana University investigators conducting clinical trials/studies as defined by the Food and Drug Administration, International Committee of Medical Journal Editors, National Institutes of Health or submitting qualified research billing claims to the Centers for Medicare and Medicaid Services.

Policy Statement

Indiana University is committed to fostering compliance with requirements concerning the public availability of clinical trial data on ClinicalTrials.gov. This policy is in support of requirements from the Food and Drug Administration, National Institutes of Health, International Committee of Medical Journal Editors and Centers for Medicare and Medicaid Services (CMS).

Reason For Policy

To foster a compliant environment that adheres to applicable federal regulations and policies related to the registration and maintenance of clinical trials in ClinicalTrials.gov.

Procedure

The Office of Research Compliance (ORC) in collaboration with the Clinical and Translational Sciences Institute (CTSI) provides administration, monitoring, auditing, training and oversight to foster compliance with FDAAA and NIH. The research community has the responsibility to create and maintain records in ClinicalTrials.gov while making determinations about registrations required to comply with ICMJE and CMS. Additionally, the research community must notify ORC when there is an external agency notification and when a Principal Investigator/Responsible Party personnel change on a ClinicalTrials.gov record has occurred.

All procedures are outlined in the Indiana University, ClinicalTrials.gov Compliance Program Plan. Office of Research Compliance: <http://researchcompliance.iu.edu/index.html>.

Definitions

Food and Drug Administration (FDA), Food and Drug Administration Amendments Act (FDAAA) Applicable Clinical Trial (ACT) is defined as

- a. Drug/Biologic – a controlled, clinical investigation, other than a phase I clinical investigation, of a drug subject to section 505 of the Federal Food, Drug, and Cosmetic Act or to section 351 of the Public Health Service Act, where ‘clinical investigation’ has the meaning given in 21 CFR 312.3 (or any successor regulation) and ‘Phase I’ has the meaning given in 21 CFR 312.21 (or any successor regulation) .
- b. Device – a prospective clinical study of health outcomes comparing an intervention with a device subject to section 510(k), 515, or 520(m) of the Federal Food, Drug, and Cosmetic Act against a control in human subjects (other than a small clinical trial to determine the feasibility of a device, or a clinical trial to test prototype devices where the primary outcome measure relates to feasibility and not to health outcomes); and a pediatric postmarket surveillance of a device as required under section 522 of the Federal Food, Drug, and Cosmetic Act.

ClinicalTrials.gov is a public registry developed by the National Library of Medicine (NLM) as part of a mandate from the Food and Drug Administration Modernization Act (FDAMA) and further enhanced to include a results database as part of a mandate from FDAAA.

Primary Completion Date is defined as the date that the final subject was examined or received an intervention for the purposes of final collection of data for the primary outcome measure.

International Committee of Medical Journal Editors (ICMJE) clinical trial is defined as any research project that prospectively assigns people or a group of people to an intervention, with or without concurrent comparison or control groups, to study the cause-and-effect relationship between a health-related intervention and a health outcome.

Enrollment is typically defined as placing a consenting a human research subject into a clinical trial.

National Institutes of Health (NIH) clinical trial is defined as a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes.

National Clinical Trial Number is an eight-digit number initiated with the acronym NCT that is assigned to identify the record and is issued when the record registration is publically posted on ClinicalTrials.gov.

Protocol Registration and Results System (PRS) is the internal system where data entry is completed prior to the public posting of the record on ClinicalTrials.gov. Each sponsoring entity has an assigned PRS organizational account.

Responsible Party is identified as the entity or individual who is responsible for registering a clinical trial and submitting clinical trial data to ClinicalTrials.gov.

Principal Investigator is identified as the responsible leader of a team of investigators (and research team) who has the ultimate responsibility for the conduct of the research. The Principal Investigator is delegated the Responsible Party role and assumes the associated responsibilities on an Indiana University or investigator initiated clinical trial.

Sanctions

Indiana University Principal Investigators that fail to comply with the requirements may be subject to enforcement actions. Failure to comply with FDAAA requirements may result in financial penalties, withholding of funds and sanctions imposed by the FDA. Failure to comply with NIH may result in withholding of cash payments, disallowing cost for an activity, suspending or terminating either in part or whole the current award, withholding a future award and having a non-compliance notice publically available. Failure to comply with ICMJE requirements may result in an inability to publish in an ICMJE affiliated journal. Failure to comply with CMS requirements can result in a lack of payment for a qualified research billing service and a need to refile the qualified research billing claim. Indiana University reserves the right to impose discipline or sanctions, up to and including termination, as provided for in applicable university policies.

History

This policy was established in July 2016 and revised in January 2017.

Previous Versions:

[Effective Dates: 07/01/2016 - 01/04/2017](#)

Related Information

[ClinicalTrials.gov Main Site](#)

[ClinicalTrials.gov Researchers Help Site](#)

[ClinicalTrials.gov PRS Log-in Site](#)

[Office of Research Compliance Site](#)

[Indiana University, ClinicalTrials.gov Compliance Program Site](#)

[Indiana University, ClinicalTrials.gov Compliance program Plan](#)